

DEC 30 2020

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

Clerk, U. S. District Court
Eastern District of Tennessee
At Greeneville

UNITED STATES OF AMERICA)

v.)

STERLING KNIGHT)
PHARMACEUTICALS, LLC)

No. 2:20-cr-113

Judge: Greer/Wynick

PLEA AGREEMENT

The United States of America, by the United States Attorney for the Eastern District of Tennessee (“USATNE”), the United States Department of Justice, Consumer Protection Branch (“USDOJ-CPB”), the defendant, STERLING KNIGHT PHARMACEUTICALS, LLC, and the defendant’s attorneys, A. Lee Bentley, III and Jason P. Mehta, have agreed upon the following:

1. The defendant will waive indictment and arraignment and plead guilty to an information charging the defendant with the following offense:

(a) Count One – Conspiracy to Commit Health Care Fraud: the defendant knowingly, intentionally, and unlawfully conspired with one or more other persons to commit Health Care Fraud in violation of 18 U.S.C. § 1347, and one or more such persons did an act to effect the object of the conspiracy, all in violation of 18 U.S.C. § 371. The maximum punishment for this offense is a fine not to exceed \$500,000 or twice the gross gain or gross loss resulting from the offense, whichever is greatest (*see* 18 U.S.C. § 3571(c), (d)), and a \$400 special assessment (*see* 18 U.S.C. § 3013(a)(2)(B)).

2. In consideration of the defendant’s guilty pleas:

(a) USATNE agrees not to further prosecute the defendant in the Eastern District of Tennessee for any other non-tax criminal offenses committed by the defendant that

are related to the charges contained in the information in this case and that are known to USATNE at the time this plea agreement is signed by both parties.

(b) USDOJ-CPB agrees not to further prosecute the defendant in any district in the United States for any other non-tax criminal offenses committed by the defendant that are related to the charges contained in the information in this case and that are known to USDOJ-CPB at the time this plea agreement is signed by both parties.

3. The defendant has read the information, discussed the charge and possible defenses with defense counsel, and understands the crime charged.

4. In support of the defendant's guilty plea, USATNE, USDOJ-CPB, and the defendant agree and stipulate to the following facts, which satisfy the offense elements. These are the facts submitted for purposes of the defendant's guilty plea. They do not necessarily constitute all of the facts in the case. Other facts may be relevant to sentencing. The defendant, USATNE, and USDOJ-CPB retain the right to present additional facts to the Court to ensure a fair and appropriate sentence in this case.

(a) From on or about June 1, 2016 through on or about April 1, 2018, the defendant conspired with HealthRight LLC, Scott Roix, Larry Everett Smith, Alpha-Omega Pharmacy LLC ("Alpha-Omega"), Germaine Pharmacy Inc. ("Germaine"), ERX Consultants LLC dba Zoetic Pharmacy ("Zoetic"), Tanith Enterprises LLC ("Tanith"), ULD Wholesale Group ("ULD"), Arun Kapoor, Mihir Taneja, and others to implement a scheme and artifice to knowingly and intentionally defraud health care benefit programs into paying for misbranded prescription drugs that had been introduced into interstate commerce, including, without limitation, by causing them to be mailed from Florida to the Eastern District of Tennessee.

(b) The deceived health care benefit programs include the pharmacy benefit managers (“PBMs”) CVS Caremark, Express Scripts, MedImpact, Prime Therapeutics, and others.

(c) During the time period of this conspiracy, the defendant was operated by Arun Kapoor and Mihir Taneja as a “virtual manufacturer” to label and distribute prescription drugs and other products manufactured by third parties.

(d) Among other products, Sterling Knight labeled and packaged several products, including Fenortho 200 mg capsules (NDC: 69336-0113-10), Lidopril (69336-0825-01), Lidopril XR (NDC: 69336-0826-01), Lidocaine 5% (NDC: 69336-0103-35), Durachol (69336-03-0030), and Cifrazol (69336-03-1030).

(e) Fenortho, Lidopril, Lidopril XR, and Lidocaine were all prescription “drugs” as that term is defined in 21 U.S.C. § 321(g)(1). In particular, they were (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; or (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; or (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

(f) Durachol and Cifrazol were not prescription drugs, but were instead non-prescription vitamin capsules containing 1 mg of folic acid and 3,775 units of Vitamin D. The defendant bought millions of these vitamin capsules from a manufacturer that was not licensed by the Food and Drug Administration (“FDA”) to manufacture drugs.

(g) The defendant then repackaged these non-prescription vitamins as prescription-only drugs, assigned them a national drug code (“NDC”), branded them with the Sterling Knight label and the brand names “Durachol” and “Cifrazol”, and bottled them in 30-count bottles, with the intent to sell them to wholesalers and pharmacies as though they were prescriptions drugs, knowing that those pharmacies would then bill them to PBMs as though they were prescription drugs.

(h) The defendant fraudulently registered Durachol and Cifrazol as prescription drugs with the FDA, First Databank, and Medispan, even though it knew that these products were not prescription drugs. Doing this was essential in order to increase the likelihood that the PBMs would pay for them.

(i) The defendant then sold thousands of bottles of Durachol and Cifrazol to Smith and his wholesaler, ULD Wholesale, knowing and intending that Smith would dispense them to patients throughout the United States, including in the Eastern District of Tennessee.

(j) Beginning on or about the summer of 2015, the defendant knew that Mihir Taneja, Larry Smith and Scott Roix agreed that Scott Roix would use the HealthRight telemarketing platform to obtain thousands of electronic prescriptions specifically for the products distributed by the defendant, specifically Fenorthol, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol.

(k) Scott Roix then obtained thousands of those prescriptions by using HealthRight’s telemarketing platform to deceive patients into providing their personal prescription insurance information to HealthRight, including by placing fraudulently misleading ads on various websites.

(l) Roix then sold those prescriptions to Larry Smith for approximately \$500 for each of those prescriptions.

(m) At all times during the conspiracy, the defendant knew that Scott Roix was providing signed doctors prescriptions to Alpha-Omega, Germaine, and Zoetic for Sterling Knight's products – Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol – even though: (i) the patients were rarely speaking with the prescribing doctors; (ii) the patients had no pre-existing relationship with the prescribing doctors; (iv) the prescriptions that resulted from Roix's and HealthRight's telemarketing platform were not issued pursuant to a valid doctor-patient relationship; and (v) the patients didn't know they would be receiving prescriptions in the mail.

(n) After arranging for the purchase of prescriptions from Scott Roix, the defendant, Mihir Taneja, and Larry Smith needed a way to bill the PBMs for these prescriptions.

(o) On July 7, 2016, May 26, 2017, and July 3 2017, the defendant knew that Mihir Taneja and Larry Smith arranged for trusted confederates – in particular three men whose initials are B.H., S.C., and K.C. – to purchase Alpha-Omega, Germaine, and Zoetic using money borrowed from a financial institution pursuant to personal guarantees from Mihir Taneja and Smith.

(p) Mihir Taneja and Smith arranged for this “straw ownership” because they knew that the PBMs would terminate their contracts with Alpha-Omega, Germaine, and Zoetic – thereby eliminating their ability to bill for prescriptions – if they knew that Smith owned and controlled them. Mihir Taneja and Smith knew this because, prior to the conspiracy, Smith owned a pharmacy that was investigated for fraud, some of the PBMs, including Express Scripts, found out about the investigation, and terminated that prior pharmacy. Mihir Taneja knew that

Smith controlled the day-to-day operations of Alpha-Omega, Germaine, and Zoetic using Smith's company, Tanith.

(q) Mihir Taneja and Larry Smith also agreed that the defendant would provide Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol to Larry Smith so that he had a product to dispense to the deceived patients after buying corresponding fraudulent prescriptions from Scott Roix.

(r) The defendant sold Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol to Larry Smith's company, ULD Wholesale, knowing that Smith then mailed these products from Alpha-Omega, Germaine, and Zoetic to patients throughout the United States, even though these prescriptions were not issued pursuant to a valid doctor-patient relationship and even though the patients didn't know they were going to receive prescriptions in the mail.

(s) The defendant knew that Larry Smith, through Tanith, caused Alpha-Omega, Germaine, and Zoetic to fraudulently bill the PBMs for the prescriptions purchased from Scott Roix for Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol, even though these prescriptions were not issued pursuant to a valid doctor-patient relationship.

(t) From on or about June 1, 2016 through the end of 2017, the defendant continued to sell Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol to Smith, knowing and intending that these products would be dispensed to patients throughout the United States, even though they were prescribed in the absence of a doctor-patient relationship.

(u) The defendant, Taneja, Kapoor, and Smith also knew that when billing the PBMs for prescriptions, Alpha-Omega, Germaine, and Zoetic were required to collect patient copays, and that if they weren't able to do so, the PBMs would terminate those pharmacies' ability to bill for prescriptions. However, the defendant, Taneja, Kapoor, and Smith also knew

that the patients would not actually pay the copays because the vast majority didn't actually want to receive, or didn't know that they were going to receive, prescriptions for Fenortho, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol.

(v) To address this problem, Taneja and Kapoor agreed with Smith to make it appear as though the defendant paid a "manufacturers' coupon" for the full amount of each patient copay for the thousands of prescriptions purchased from Roix. Taneja and Kapoor then caused the defendant to establish a relationship with a third-party manufacturers' coupon rebate facilitator ("Rebate Facilitator #1"). Rebate Facilitator #1 was already in the business of processing legitimate manufacturers' coupons on behalf of pharmaceutical manufacturers and paying the proceeds obtained from the manufacturers to pharmacies that were able to submit the manufacturers' coupon.

(w) In a *bona fide* manufacturers' coupon: (i) the patients bring the coupon to the pharmacy, having obtained it directly from a doctor or the manufacturer; (ii) the pharmacy submits an electronic claim to Rebate Facilitator #1 with the presented coupon code; (iii) Rebate Facilitator #1 cross-references the coupon code with its list of enrolled pharmaceutical manufacturers to determine how much to pay the pharmacy for the copay coupon; (iv) Rebate Facilitator #1 then pays the coupon amount to the pharmacy with a remittance indicating that the payment is for the patients' copay; and (v) Rebate Facilitator #1 then collects that copay coupon amount from the manufacturer, which bears the economic cost of the copay coupon.

(x) In this situation, however, as Taneja, Kapoor, the defendant, and Smith knew, the patients never knew about any coupon, never spoke to a doctor, never heard of the defendant, and never presented anything to Alpha-Omega, Germaine, or Zoetic. Moreover,

Smith's pharmacies (Alpha-Omega, Germaine, and Zoetic) not the manufacturer (the defendant) funded the entirety of the copay coupon, a direct and intentional fraud upon the PBMs.

(y) Taneja and Kapoor provided the defendant's Rebate Facilitator #1 coupon code directly to Smith who, in turn, caused Alpha-Omega, Germaine, and Zoetic to submit claims for the manufacturers' coupon to Rebate Facilitator #1 for essentially every single prescription purchased from Roix. Rebate Facilitator #1 processed those coupons, obtained reimbursement from the defendant, and paid the resulting amount to the submitting pharmacy – Alpha-Omega, Germaine, and Zoetic.

(z) But, although the defendant sent money to Rebate Facilitator #1, it didn't actually bear the economic cost of that payment. Instead, Taneja and Kapoor, upon receiving invoices from Alpha-Scrip, simply forwarded those invoices to Smith and told him to pay them, which Smith did using the money he extracted from Alpha-Omega, Germaine, and Zoetic's bank accounts.

(aa) Thus, Taneja and Kapoor caused the defendant to help Smith launder money from Smith's pharmacies, through the defendant and Rebate Facilitator #1, back to Smith's pharmacies, all for the purpose of obtaining the remittance indicating that the patients' copays had been paid, which was false. This was done for the purpose of deceiving the PBMs into believing that the patients' copays had been paid, which was false.

(bb) In sum, as the defendant knew and intended, Smith's pharmacies paid the patients' copays to themselves, as there was no economic substance to the defendant's involvement in the process – its only purpose being to disguise the nature and origin of the payment and to pass it off, falsely, as a *bona fide* a manufacturers' coupon. During the

conspiracy, this process was repeated for the full amount of thousands of patient copays for prescriptions purchased from Roix.

(cc) In particular, on or about September 19, 2017, the defendant, with the intent to defraud and mislead, introduced, delivered, and caused to be introduced and delivered, into interstate commerce from Florida to the Eastern District of Tennessee, Cifrazol 3,775-1mg cap (NDC: 69336-0310-30), a drug that was misbranded in that its labeling was false and misleading in any particular (including, without limitation, in that it stated falsely that the product could only be taken pursuant to a prescription) and was dispensed to patient B.N. without a valid prescription of a practitioner licensed by law to administer such drug, which Alpha-Omega billed fraudulently to CVS Caremark and for which CVS Caremark paid Alpha-Omega approximately \$1,464.

(dd) The defendant understood that health care benefit programs, as defined by 18 U.S.C. § 24(b), would reimburse for prescriptions pursuant to this scheme. Private insurance companies and self-insured groups are health care benefit programs. However, the defendant intended that no “federal health care program,” as defined by 42 U.S.C. § 1320a-7b(f), would reimburse for Fenorthol, Lidopril, Lidopril XR, Lidocaine, Durachol, and Cifrazol or other Sterling Knight products. Because the defendant knew that the federal government imposed stricter regulatory requirements and had greater oversight than private health care benefit programs, the defendant went to lengths to ensure that no representations or claims were made to federal health care programs by itself, Alpha-Omega, Germaine, or Zoetic in connection with this scheme. In reality, federal health care programs made only modest and insubstantial payments to Alpha-Omega, Germaine, and Zoetic for Sterling-Knight products as part of this scheme. USATNE and USDOJ-CPB are unaware of any statements or claims made by the

defendant or Mihir Taneja to any federal health care program in connection with this scheme. The defendant does not have any knowledge as to whether or not Andrew Assad, Peter Bolos, Michael Palso, Synergy, or Precision took any steps to prevent claims from being submitted to federal health care benefit programs as part of this scheme.

(ee) As a result of billing the PBMs for misbranded prescription drugs, the pharmacies that were part of this conspiracy caused an actual loss to the PBMs in the amount of \$20,981,786. This is the full amount that the PBM's paid to all pharmacies for invalid prescriptions purchased from Scott Roix and HealthRight for products manufactured or distributed by the defendant.

(ff) The defendant knew that had the PBMs not been defrauded in the various ways described in this plea agreement, they would not have paid for claims for payment submitted by the pharmacies for prescriptions that were written in the absence of a valid doctor-patient relationship (including in the absence of any real communication between the prescribing doctor and the patient), for products that had been misbranded and fraudulently packaged as prescription drugs, and dispensed to patients who were deceived into providing their insurance information and who didn't want such products in the first place.

(gg) The duly authorized representative of the defendant identified below has personal knowledge of many but not all of the facts set forth in this paragraph 4. In advance of signing this plea agreement on behalf of the defendant, the duly authorized representative has confirmed the accuracy of all the facts set forth in this paragraph 4.

5. The defendant is pleading guilty because the defendant is in fact guilty. The defendant understands that, by pleading guilty, the defendant is giving up several rights, including:

- (a) the right to have his case presented to a grand jury for these crimes;
- (b) the right to plead not guilty;
- (c) the right to a speedy and public trial by jury;
- (d) the right to assistance of counsel at trial;
- (e) the right to be presumed innocent and to have the burden of proof placed on the United States to prove the defendant guilty beyond a reasonable doubt;
- (f) the right to confront and cross-examine witnesses against the defendant;
- (g) the right to testify on one's own behalf, to present evidence in opposition to the charges, and to compel the attendance of witnesses; and
- (h) the right not to testify and to have that choice not used against the defendant.

6. The parties agree that the appropriate disposition of this case would be the following as to each count:

- (a) The Court may impose any lawful terms of probation and any lawful fines up to the statutory maximums. Pursuant to Rule 11(c)(1)(B), and in consideration of the terms of this plea agreement (and taking into account the provisions of 18 U.S.C. § 3571(c) and (d), and the related fact that the defendant has agreed to pay restitution in advance of sentencing in the amount specified in this plea agreement) and the policy statement set forth in U.S.S.G. § 6B1.2(b) and related commentary, USATNE and USDOJ-CPB agree to recommend at the time of sentencing that any fine imposed by the Court not exceed \$500,000.
- (b) The Court will impose special assessment fees as required by law; and
- (c) The Court may order forfeiture as applicable (see paragraph 10) and restitution as appropriate (see paragraph 9).

(d) No promises have been made by any representative of USATNE or USDOJ-CPB to the defendant as to what the sentence will be in this case. Any estimates or predictions made to the defendant by defense counsel or any other person regarding any potential sentence in this case are not binding on the Court, and may not be used as a basis to rescind this agreement or withdraw the defendant's guilty plea. The defendant understands that the sentence in this case will be determined by the Court after it receives the presentence investigation report from the United States Probation Office and any information presented by the parties. The defendant acknowledges that the sentencing determination will be based upon the entire scope of the defendant's criminal conduct, the defendant's criminal history, and pursuant to other factors and guidelines as set forth in the Sentencing Guidelines and the factors set forth in 18 U.S.C. § 3553.

7. Given the defendant's agreement to plead guilty, USATNE and USDOJ-CPB will not oppose a two-level reduction for acceptance of responsibility under the provisions of § 3E1.1(a) of the Sentencing Guidelines. Further, if the defendant's offense level is 16 or greater, and the defendant is awarded the two-level reduction pursuant to § 3E1.1(a), USATNE and USDOJ-CPB agree, at or before the time of sentencing, to move the Court to decrease the offense level by one additional level pursuant to § 3E1.1(b) of the Sentencing Guidelines. Should the defendant engage in any conduct or make any statements that are inconsistent with accepting responsibility for the defendant's offense, including violations of conditions of release or the commission of any additional offense(s) prior to sentencing, USATNE and USDOJ-CPB will be free to decline to make such motion, to withdraw that motion if already made, and to recommend to the Court that the defendant not receive any reduction for acceptance of responsibility under § 3E1.1 of the Sentencing Guidelines.

8. The defendant agrees to pay the special assessment in this case prior to sentencing.

9. The defendant agrees that the Court shall order restitution, pursuant to any applicable provision of law, for any loss caused to: (1) the victims of any offense charged in this case; and (2) the victims of any criminal activity that was part of the same course of conduct or common scheme or plan as the defendant's charged offense. Pursuant to Rule 11(c)(1)(B) of the Federal Rules of Criminal Procedure, the parties agree to recommend that the defendant be responsible, jointly and severally with Mihir Taneja and Arun Kapoor, for restitution in the amount of \$20,981,786, which is the full amount that the PBM's paid to all pharmacies for invalid prescriptions purchased from Scott Roix and HealthRight for products manufactured or distributed by the defendant. The proposed restitution amounts described in this paragraph correspond to actual losses sustained by the health care benefit programs and their agents, the PBMs, as a result of the defendant's actions described in this plea agreement.

10. Unless otherwise limited by an agreed preliminary order of forfeiture, the defendant agrees to the entry of a money judgment against it, and in favor of the United States, at the time of sentencing. This money judgment will represent assets in the possession or control of the defendant or the defendant's nominees and that were derived, directly or indirectly, from proceeds traceable to the commission of a violation of 18 U.S.C. § 371. Specifically, the defendant agrees, in full satisfaction of its forfeiture obligations in this matter, to the following:

A personal money judgment in favor of the United States and against the defendant, STERLING KNIGHT PHARMACEUTICALS, LLC, in the amount of \$6,168,398, which represents the amount of proceeds the defendant personally obtained from the offense described above.

The defendant agrees to pay the \$6,168,398 to the United States Marshals Service at the time of sentencing.

The United States agrees that the monies paid by the defendant in forfeiture shall be credited against the amount due by the defendant in restitution. In sum, if the defendant pays the \$6,168,398 due as forfeiture, its restitution obligations, as described herein, shall be reduced by that amount.

If the defendant fails to pay the \$6,168,393 due at the time of sentencing, the defendant agrees to the provisions set forth in this paragraph. First, the defendant agrees to assist the United States fully in the identification, recovery, and return to the United States of any other assets or portions thereof subject to forfeiture. The defendant further agrees to make a full and complete disclosure of all assets over which the defendant exercises control and those which are held or controlled by a nominee. The defendant further agrees to forfeit all interests as described above and to take whatever steps are necessary to pass clear title to the United States. These steps include, but are not limited to, the surrender of title, the signing of a consent decree of forfeiture, and the signing of any other documents necessary to effectuate such transfers. The defendant further agrees not to object to any civil or criminal forfeiture brought against these properties. Finally, the defendant agrees to take all such steps to locate such property and to pass title to the United States before the defendant's sentencing.

In the event a money judgment forfeiture is ordered, the defendant agrees to send all money judgment payments to the United States Marshals Service. Defendant also agrees that the full money judgment amount shall be considered due and payable immediately. If the defendant cannot pay the full amount immediately, the defendant agrees that the United States will have the authority to establish payment schedules to ensure payment of the money judgment. The defendant further agrees to cooperate fully in efforts to collect on the money judgment by set-off of federal payments, execution on non-exempt property, and any other means the United States

deems appropriate. The defendant and counsel also agree that the defendant may be contacted post-judgment regarding the collection of the money judgment without notifying defendant's counsel and outside the presence of the defendant's counsel.

11. The defendant agrees to pay all fines and restitution imposed by the Court to the Clerk of Court. The defendant also agrees that the full fine and/or restitution amount(s) shall be considered due and payable immediately. Notwithstanding any provision of this agreement to the contrary, the defendant agrees to pay the full amount of restitution to the Court, at or before the sentencing. If the defendant cannot pay the full amount immediately, the defendant agrees that Probation Office will have the authority to establish payment schedules to ensure payment of the fine and/or restitution. The defendant further agrees to cooperate fully in efforts to collect any financial obligation imposed by the Court by set-off of federal payments, execution on non-exempt property, and any other means the United States deems appropriate. The defendant and counsel also agree that the defendant may be contacted post-judgment regarding the collection of any financial obligation imposed by the Court without notifying the defendant's counsel and outside the presence of the defendant's counsel. In order to facilitate the collection of financial obligations to be imposed with this prosecution, the defendant agrees to disclose fully all assets in which the defendant has any interest or over which the defendant exercises control, directly or indirectly, including those held by a nominee or other third party. In the event that the defendant fails to fulfill any financial obligation under this agreement in a timely fashion, the defendant additionally agrees to the following specific terms and conditions:

(a) If so requested by USATNE or USDOJ-CPB, the defendant will promptly submit a completed financial statement to USATNE and USDOJ-CPB, in a form it or they

provide and as it or they direct. The defendant promises that such financial statement and disclosures will be complete, accurate, and truthful.

(b) The defendant expressly authorizes USATNE and USDOJ-CPB to obtain a credit report on the defendant in order to evaluate the defendant's ability to satisfy any financial obligation imposed by the Court.

(c) If so requested by USATNE or USDOJ-CPB, the defendant will promptly execute authorizations on forms provided by USATNE and USDOJ-CPB to permit USATNE and USDOJ-CPB to obtain financial and tax records of the defendant.

12. The defendant understands that if the defendant holds any regulatory licenses or permits, or is contracted with any federal, state, or local governmental entity, the conviction in this case may result in the suspension or revocation of those licenses and permits or the termination of those contracts. The defendant understands that the defendant may not use anticipated or unanticipated collateral consequences such as these as a basis for withdrawing the defendant's guilty plea.

13. Within three (3) business days' of the public filing of this fully-signed plea agreement, the defendant shall make this plea agreement and the associated information conspicuously available to the public on the home page of its primary website for four (4) consecutive years, and shall communicate to all of defendant's employees that it has entered into this agreement and make available the information and this agreement.

14. The defendant agrees that, effective upon the later to occur of either the sentence of the defendant in this matter or January 1, 2022, it shall not engage in the distribution, dispensing, or sale of any drugs or dietary supplements for the duration of any term of probation assigned by the Court in this matter. In the interim, to the extent that the defendant does engage

in the distribution, dispensing, or sale of any drugs or dietary supplements, the defendant also agrees that it shall adopt reasonable policies and procedures to ensure that it and its employees do not commit further violations of any federal law and do not facilitate the commission of fraud or deceit against any health care benefit program in connection with the sale, distribution, or dispensing of the defendant's products. These policies and procedures shall ensure, among other things, that the defendant: (a) does not cause any food product to be incorrectly branded or packaged as a drug or prescription drug; (b) does not promote, sponsor, or facilitate any copay coupon program, or other similar program, except to the extent that such copay coupon complies with all applicable laws and regulations; and (c) takes reasonable measures to ensure that any copay coupon program, or other similar program, promoted, sponsored, or facilitated by the defendant is not used by any pharmacy or wholesaler to subvert any obligation under any provider manual, provider agreement, or other agreement governing the relationship between such entity and any health care benefit program, or to defraud or deceive any health care benefit program. The defendant shall ensure that all its employees are aware of and familiar with these policies and procedures on at least an annual basis.

15. This agreement shall bind the defendant, its successor entities (if any), parent companies to the extent they assume the liabilities contained herein, and any other person or entity that assumes the liabilities contained herein ("successors-in-interest"). The defendant, or its successors-in-interest, if applicable, shall provide USATNE and USDOJ-CPB with immediate notice of any name change, business reorganization, sale or purchase of assets, divestiture of assets, or similar action affecting the defendant's ability to pay any fine ordered by the Court or affecting this agreement. No change in name, change in corporate or individual control, business reorganization, change in ownership, merger, change of legal status, sale or purchase of assets, or

similar action shall alter the defendant's responsibilities under this agreement. The defendant shall not engage in any action to seek to avoid the obligations and conditions set forth in this agreement. If such transaction or series of transactions has the effect of circumventing or frustrating the purposes of this agreement, as determined in the sole discretion of USATNE or USDOJ-CPB, it shall be deemed a breach of this agreement.

16. The defendant acknowledges that the principal benefits to USATNE and USDOJ-CPB of this agreement include the conservation of limited government resources and bringing a certain end to the case. Accordingly, in consideration of the concessions made by USATNE and USDOJ-CPB in this agreement and as a further demonstration of the defendant's acceptance of responsibility for the offense committed, the defendant voluntarily, knowingly, and intentionally agrees to the following:

(d) The defendant will not file a direct appeal of the defendant's conviction or sentence with one exception: The defendant retains the right to appeal a sentence imposed above the sentencing guideline range determined by the Court or above any mandatory minimum sentence deemed applicable by the Court, whichever is greater. The defendant also waives the right to appeal the Court's determination as to whether the defendant's sentence will be consecutive or partially concurrent to any other sentence.

(e) The defendant will not file any motions or pleadings pursuant to 28 U.S.C. § 2255 or otherwise collaterally attack the defendant's conviction or sentence, with two exceptions: The defendant retains the right to file a § 2255 motion as to (i) prosecutorial misconduct and (ii) ineffective assistance of counsel.

(f) The defendant will not, whether directly or by a representative, request or receive from any department or agency of the United States any records pertaining to the

investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

17. This plea agreement becomes effective once it is signed by the parties and is not contingent on the defendant's entry of a guilty plea. The defendant's signature on this plea agreement constitutes the defendant's admission that the facts contained herein are true and accurate. If USATNE or USDOJ-CPB violate the terms of this agreement, the defendant will have the right to withdraw from this agreement. If the defendant violates the terms of this agreement in any way (including, without limitation, by failing to enter a guilty plea as agreed herein, moving to withdraw guilty plea after entry, or by violating any court order or any local, state, or federal law pending the resolution of this case), then USATNE or USDOJ-CPB will have the right to void any or all parts of the agreement and may also enforce whatever parts of the agreement it chooses. In addition, USATNE or USDOJ-CPB may prosecute the defendant for any and all federal crimes that the defendant committed related to this case, including any charges that were dismissed and any other charges that USATNE and USDOJ-CPB agreed not to pursue. The defendant expressly waives any statute of limitations defense and any constitutional or speedy trial or double jeopardy defense to prosecution for the conduct contemplated by this agreement. The defendant also understands and agrees that a violation of this agreement by the defendant does not entitle the defendant to withdraw the defendant's guilty plea in this case.

18. The United States will file a supplement in this case, as required in every case by the Local Rules of the United States District Court for the Eastern District of Tennessee, even though there may or may not be any additional terms. If additional terms are included in the supplement, they are hereby fully incorporated herein.

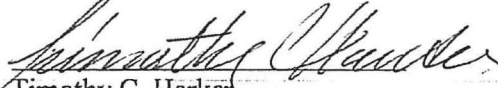
19. This plea agreement and supplement constitute the full and complete agreement and understanding between the parties concerning the defendant's guilty plea to the above-referenced charges, and there are no other agreements, promises, undertakings, or understandings between the defendant and the United States. The parties understand and agree that the terms of this agreement can be modified only in writing signed by all of the parties and that any and all other promises, representations, and statements whether made before, contemporaneous with, or after this agreement, are null and void.

* * * * *


J. Douglas Overbey
United States Attorney

For USATNE:

12/3/2020
Date

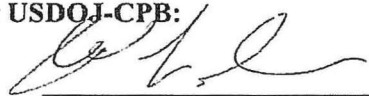
By: 
Timothy C. Harker
Assistant United States Attorney

Date

By: 
Mac D. Heavener, III
Assistant United States Attorney

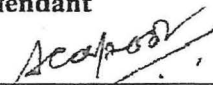
For USDOJ-CPB:

12/03/20
Date

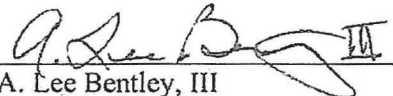

David L. Gunn
Trial Attorney
U.S. Department of Justice
Consumer Protection Branch

For the Defendant

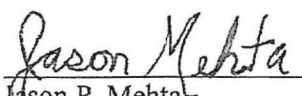
11/30/2020
Date


Arun Kappor
Duly Authorized Representative of
the defendant Sterling Knight
Pharmaceuticals LLC

11/30/2020
Date


A. Lee Bentley, III
Attorney for the defendant Sterling Knight
Pharmaceuticals, LLC

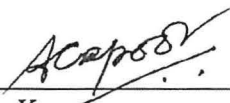
11/30/20
Date


Jason P. Mehta
Attorney for the defendant Sterling Knight
Pharmaceuticals, LLC

Signature Page to Sterling-Knight Pharmaceuticals, LLC Plea Agreement

Certification of the Defendant

I have been duly authorized according to the bylaws and relevant organizational documents of the defendant Sterling Knight Pharmaceuticals, LLC ("the defendant") to enter into this agreement on behalf of the defendant. I have read this agreement in its entirety. I have had enough time to review and consider this agreement, and I have carefully and thoroughly discussed every part of it with the defendant's attorney. I understand the terms of this agreement, and I voluntarily agree to those terms on behalf of the defendant. I have discussed the evidence with the defendant's attorney, and defendant's attorney has advised me of defendant's rights, of possible pretrial motions that might be filed, of possible defenses that might be asserted either prior to or at trial, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement. No promises, inducements, or representations of any kind have been made to me or to the defendant other than those contained in this agreement. No one has threatened or forced me or the defendant in any way to enter into this agreement. I am satisfied with the representation of the defendant's attorney in this matter, and I am pleading guilty on behalf of the defendant because the defendant is guilty of the charge and wishes to take advantage of the promises set forth in this agreement, and not for any other reason.



Arun Kapoor

Date: 11/30/2020

A duly authorized representative of the
defendant Sterling Knight Pharmaceuticals, LLC